disabilities

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Study Protocol

The Effects of a Multi-Sports Program on the Physical Fitness, Quality of Life, and Well-Being of People with Intellectual and Developmental Disabilities—A Study Protocol

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Abstract: We intend to develop an intervention program based on sports for people with Intellectual and Developmental Disability (IDD) to analyze its effects on physical fitness, quality of life (QoL), and well-being. The convenience sample will consist of at least 24 participants aged between 18 and 65, of both sexes, who are institutionalized with a previous diagnosis of IDD and no associated comorbidities (e.g., visual impairment or cerebral palsy). The participants will be divided into two groups: (i) the experimental group and (ii) the control group. The experimental group will have a weekly session, lasting 60 min, for 36 weeks. There will be a baseline assessment, a final assessment, and a follow-up assessment (three months after the end of the program). The results of this study are intended to contribute to the development of more assertive community interventions, based on sports, for the benefit of this population.

Keywords: intellectual developmental disabilities; sports; quality of life; well-being; physical fitness

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1. Introduction

Intellectual and Developmental Disability (IDD) is a developmental disorder that can range in severity: it can be mild, moderate, severe, or profound. It is described by limitations in intellectual functioning and adaptive behavior, which are expressed in conceptual, practical, and social domains. These challenges typically emerge before the age of 22 [1]. This population often experiences limitations in motor performance, including difficulties with the control and manipulation of objects [2], spatial cognition and right/left distinction [3], lower isometric strength, and lower limb strength [4]. Additionally, they tend to have a higher Body Mass Index (BMI), obesity [5], and lower cardiovascular fitness [6].

Despite the well-known positive benefits of physical activity (PA), physical exercise (PE), and sports in preventing diseases such as type II diabetes, hypertension, and obesity [7–9], as well as reducing the risk of falls, reducing pain, improving joint range of motion, and achieving daily activities [10], individuals with IDD often have a sedentary lifestyle [7,11]. Low levels of PA [12,13] tend to negatively affect their quality of life (QoL) [14].

QoL is a multidimensional construct encompassing eight domains, which apply to everyone, although they could diverge individually in terms of relative value and importance. These domains include individual development; self-determination; rights; interpersonal relationships; social inclusion; and emotional, physical, and material well-being, which give rise to three factors: independence, participation, and well-being [15,16].

These domains are affected by personal characteristics and environmental factors that modify over time [16,17]. Well-being, one of the domains in this model, is a complex concept that can be examined from two complementary perspectives—objective and subjective well-being [18]. Subjective well-being includes two dimensions: an emotional dimension that concerns positive and negative affects, which represents the affect each individual manifests, as well as the prevalence of positive emotions over negative ones, and a cognitive dimension that involves life satisfaction, which agrees with the assessment the individual makes at any given moment concerning life satisfaction [19].

However, various studies have demonstrated that PA [20,21], PE [3,10], and sports [22,23] can increase the perceptions of well-being and QoL of adults with IDD. Additionally, higher levels of functional capacity appear to be linked with higher QoL values [24].

In the context of PA, in Diz et al.'s study [25], where the effects of a PA intervention program on adaptive behavior, physical fitness, and QoL in 16 adults with IDD were analyzed, and the results pointed to significant differences in the total QoL value and two physical fitness variables in the experimental group. Similar outcomes were observed in a study by Tomaszewski and colleagues [21] in which the authors found, in a sample of 38 individuals with IDD, that the domain of competence and the total QoL score were significantly correlated with weekly step count.

Regarding PE, in Carmeli et al.'s study [10], after intervention programs, where one focused on balance and the other on muscle strengthening, lasting 6 months each with a sample of 22 participants with IDD, the results showed statistically significant differences in the self-concept of well-being in the experimental group, with a multiple regression analysis indicating positive relationships between balance, muscle strength, well-being, and physical training between the experimental and control groups [10]. In addition, several systematic reviews have highlighted the benefits of PE programs in the population under study, highlighting reductions in fat mass and waist circumference and increased strength, balance, and fat-free mass as the main results [26].

With regard to the practice of sports, in a cross-sectional study carried out by Crawford et al. [22], when comparing the impacts that sports have on the psychosocial behavior and QoL of 93 people with IDD, the authors found that Special Olympics athletes presented significant differences in the total QoL score and the leisure and socialization domains when compared with individuals who did not practice any type of sport or people who practiced PE/sports but not through the Special Olympics. Moltó and Bruma [23] aimed to analyze the association between sports and life satisfaction and identify which type of sport is the most associated with life satisfaction, and they found that participants who engaged in team sports reported higher satisfaction with their lives and greater appreciation of their living conditions.

Despite the increasing research interest in the relationship between the practice of PA, PE, and sports and the QoL and well-being of individuals with IDD, there remains a significant gap in studies examining the impact of these programs (sports-based programs) on the variables mentioned [25,27]. Participation in programs that include diverse components, such as games, can encourage the frequency of practice and physical fitness [28]. Additionally, programs that involve social involvement (peers and teams) are often more motivating and facilitate practice [13]. However, there is a limited understanding of the impact that the practice of sports has on various variables, and there is still a shortage of longitudinal studies exploring its impact on the QoL, well-being, and physical fitness variables [25].

The sedentary lifestyle observed in this population under study is due to the presence of barriers that prevent or hinder the practice of PA, such as the short duration of intervention programs, reduced supply, poor adherence to sessions, as well as a lack of support from the community and a lack of motivation [13,29].

In this sense, considering the barriers and facilitators to the practice of PA by this population, it is becoming increasingly important for society to promote enjoyable programs that meet the interests and needs of individuals with IDD, keeping them motivated to practice PA in an attempt to broaden the offer, contribute to the decrease in sedentary lifestyles, and consequently promote the physical fitness, QoL, and well-being of this population.

Our study aims to analyze the effect of an intervention program based on sports on physical fitness, QoL, and well-being in institutionalized individuals with IDD. To this end, we intend to test the following hypotheses: (i) participants in the experimental group will increase their physical fitness after 36 weeks of regular sports practice; (ii) participants in the experimental group will increase their QoL after 36 weeks of regular sports practice; (iii) participants in the experimental group will increase their levels of well-being after 36 weeks of regular sports practice; (iv) there will be a difference between the control group and the experimental group in levels of physical fitness after 36 weeks; (v) there will be a difference between the control group and the experimental group in QoL after 36 weeks; and (vi) there will be a difference between the control group and the experimental group in levels of well-being after 36 weeks.

2. Materials and Methods

2.1. Design

This study protocol describes a non-randomized experimental study consisting of 2 groups, an experimental (EG) and a waitlist control (WCG). The WCG will have the opportunity to participate in the same program provided to the experimental group after the study is completed.

Participants will be allocated to one of the two groups mentioned above: the EG group, where participants will have a weekly sport-based session lasting 60 min for 36 weeks, and the WCG participants will continue to do their usual activities but will not be allowed to take part in the program promoted to individuals belonging to the experimental group.

All participants will be assessed at three different times: before the start of the intervention program (baseline), after it finishes (final assessment), and three months after the end of the intervention program (follow-up assessment).

2.2. Participants

The intervention program will involve individuals with a previous diagnosis of IDD, institutionalized in two care institutions in the Leiria region (Portugal).

The group of participants will be made up of a convenience sample of at least 24 participants in the total sample (experimental and control group with 12 participants each), aged between 18 and 65, of both sexes. Participants will be divided into two groups based on their interests and willingness to engage or not in a PE program. The number of participants was defined using the G*Power (v. 3.1.9.7.) software considering that at least 14 subjects are needed to detect an average effect size of 0.55 ($\alpha = 0.05$, $1 - \beta = 0.95$), using the ANOVA repeated measures and the within–between interaction statistical test, in agreement with the literature. An effect size was chosen based on the effect of the intervention on strength and functional capacity variables [30,31]. Considering the lack of studies investigating the impact of sport on the QoL and well-being of individuals with IDD, we used a reference with results in the other variables of interest to support the calculation of the sample's power.

Figure 1 shows the timeline for the study design.

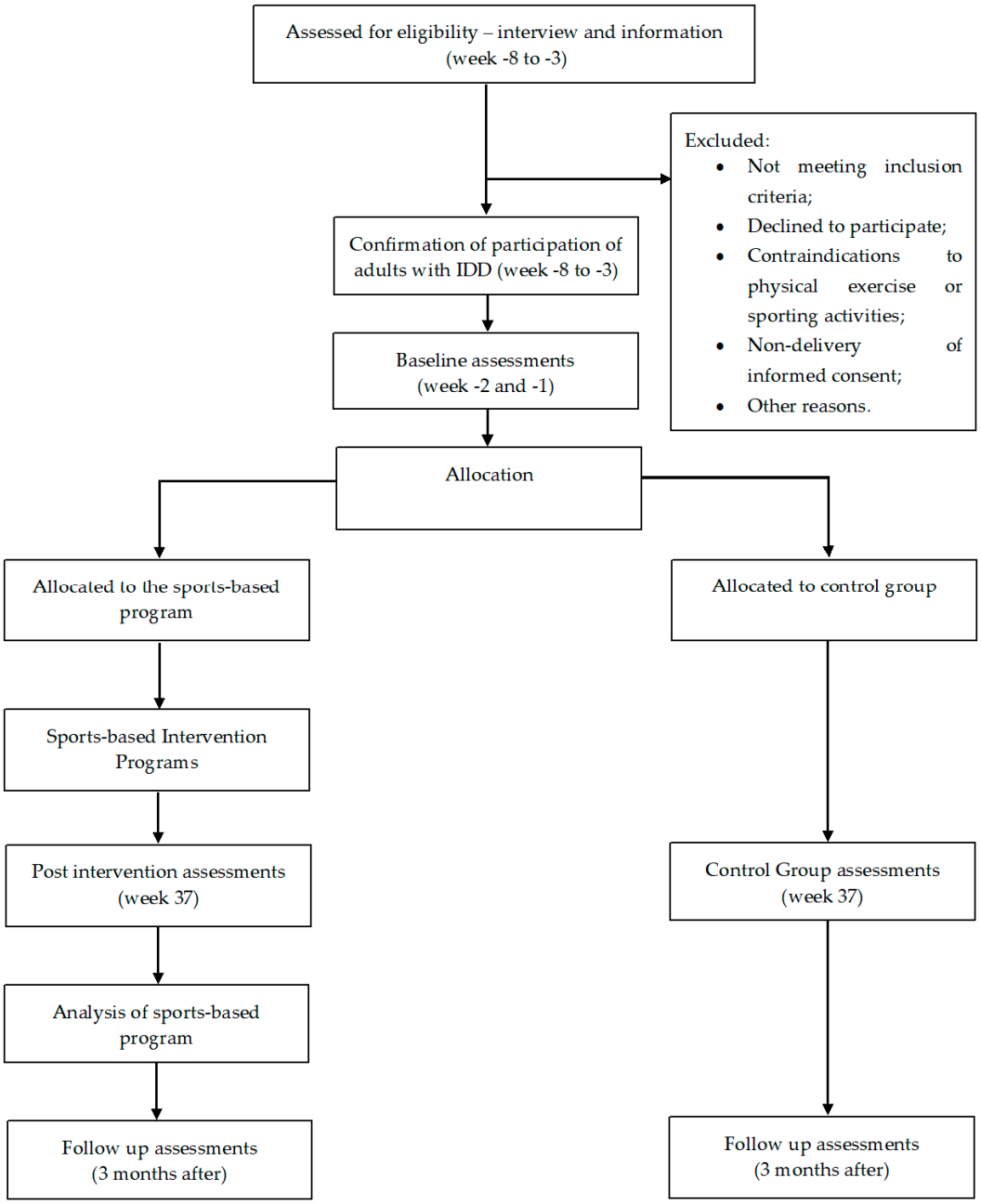

Figure 1. Timeline for the study design.

The following inclusion criteria will be defined: (1) adults with IDD, diagnosed with mild, moderate, or severe IDD; (2) age is over 18; and (3) ability to carry out the assessments. The following exclusion criteria will also be defined: (1) comorbidities such as cerebral palsy, motor disability, blindness, and deafness; (2) contraindications for physical exercise or sports; (3) inability to communicate; and (4) failure to provide signed informed consent.

2.3. Informed Consent

In addition to the explanations mentioned in the previous point, which will be carried out both with the management of the institutions and with the participants and their families/guardians, informed consent will also be given, written in simple and accessible language. This consent will contain all the information about the study, its objectives, development phases, possible risks, and benefits of participation, informing participants that they can withdraw at any time without repercussions and that participation will not

compromise their physical or psychological integrity, and ensuring the confidentiality and anonymity of the data collected.

The informed consent form mentioned in the previous paragraph will be provided to the participant, their family members/guardians, and the management of the partner institutions. Participants will be given the necessary time to consider their decision to participate in the study and will then be asked to submit their informed consent (signed or not). At any time, participants may ask questions, and it will be the responsibility of the principal investigator to address and clarify any concerns.

2.4. Protocols

The aim of this intervention program is not only to understand how sports practice influences the physical fitness, QoL, and well-being of people with IDD, but also to address some of the previously mentioned barriers that prevent or limit participation. Additionally, the program aims to integrate factors that promote engagement, prioritizing the participants' interests and preferences to keep them motivated.

The sessions will be held in the morning at a pavilion in the city of Leiria, with each institution being responsible for transporting the participants. The sessions will be structured as follows: an initial talk and warm-up (using exercises related to the sport to be trained); a fundamental part (focused on critical components of the sport); a final game (formal game); and a free period (free moment for exploration of the materials related to different sports). At the end of each session, participants will be asked to give their feedback about the session and will be given a bottle cap, which they will be asked to place in one of three boxes (box with a green smiley face, box with a yellow smiley face, and box with a red smiley face), based on their own opinion of the session.

While a set of key components is suggested for each sport and a specific number of weeks, the planning is not fixed and can be adjusted to the characteristics of the individuals, considering the difficulty or ease with which they perform the proposed exercises and progress in acquiring the skills.

To monitor session intensity, the Modified Borg Scale [32] will be used. This scale measures the participant's perceived exertion during exercise and is an important tool for monitoring the intensity of physical effort [32]. The Modified Borg Scale ranges from 0 to 10, where 0 represents no effort intensity and 10 represents maximum effort. At the end of each session, the scale will be applied to all participants so that we can monitor the intensity level of each session and ensure that it is close to the previously defined levels.

The sessions of the intervention program will be led and supervised by at least 3 technicians to guarantee the necessary support for all participants.

For more details regarding the intervention program, see Table 1.

Table 1. Intervention program protocol.

Sports Discipline	Technical Content	Critical Components	Intensities	Duration
		Week 0 and 1		
Playful Presentation Games	-	-	Light to Moderate (2–6)	60 min
		Week 2; 3; 4; 5; 18, 19; 20; 21; and 34		
Handball	-Ball handling; -Shoot; -Passing and receiving; -Dribbling; -Defensive base position; -Offensive base position; -Formal play.	-Catching and handling the ball; -Shooting in support; -Shoulder pass and bounce pass; -Two-handed reception; -Progressive dribbling; -Hand and arm placement.	Moderate to Vigorous (4–8)	60 min

Table 1. *Cont.*

Sports Discipline	Technical Content	Critical Components	Intensities	Duration
Week 6; 7; 8; 9; 22; 23; 24; 25; and 35				
Football	-Ball control and handling; -Passing and receiving; -Shooting on goal; -Dribbling; -Formal play.	-Ball control and handling; -Passing with the inside of the foot; -Passing and clearing; -Receiving with the inside of the foot; -Shooting with the inside of the foot; -Shooting with the instep; -Progressive dribbling; -Progressive dribbling with changes in direction.	Moderate to Vigorous (4–8)	60 min
Week 10; 11; 12; 13; 26; 27; 28; 29; and 36				
Basketball	-Ball handling; -Passing and receiving; -Passing and clearing; -Throwing; -Dribbling; -Defensive base position; -Offensive base position; -Formal play.	-Catching and handling the ball; -Chest pass and bounce pass; -Passing and clearing; -Two-handed reception; -Support throw, free throw, and pass throw; - Hand and arm placement; -Progressive dribbling, -Change of direction when dribbling and protective dribbling.	Moderate to Vigorous (4–8)	60 min
Week 14; 15; 16; 17; 30; 31; 32; and 33				
Volleyball	-Ball handling; -Passing and receiving; -Service; -Attack; -Defensive base position; -Offensive base position; -Formal play.	-Touch support pass; -Overhead pass and headline; -Service underneath; -Rematch; -Positioning on the block.	Moderate to Vigorous (4–8)	60 min

2.4.1. Experimental Group

The intervention program will take place in the Inclusive Pavilion of the City of Leiria, which has been adapted for the sports practice by people with disabilities. The sessions will consist of the following three distinct moments: 10 min of warm-up, with exercises related to the sport being trained; 40 min of the fundamental part, based on sports modalities; and 10 min of free time, where participants will have different materials associated with different sports available (e.g., basketballs, tennis rackets, footballs) and will be free to explore them. Finally, each participant will reflect on their participation at the end of each session.

2.4.2. Waitlist Control Group

Individuals in the WCG will be encouraged to maintain their usual daily activities and will not be allowed to take part in the intervention program sessions. After the end of the study, the WCG will have the opportunity to take part in the same program as that administered to the experimental group.

2.5. Assignment of Intervention and Blindness

Once informed consent has been signed by all parties involved and the baseline assessments have been completed, the participants will be allocated to the control and experimental groups.

Considering the nature of the intervention, once the baseline assessment is completed, it will not be possible to divide the sample randomly between the two groups and it will not be possible to hide the distribution by group from the participants and the principal investigator. However, to ensure the researchers are responsible for the assessments without this information, once the signed informed consent has been given, a code will be assigned to each participant, guaranteeing the subjects' anonymity. In this way, by keeping the same team of researchers carrying out the assessments at different times, the differences in procedures will be reduced.

2.6. Outcomes

The assessments will take place at the Lis Pavilion in Leiria in the morning. The researchers carrying out the assessments will not know what condition the participant is in (in the post-test). The participants will have eaten breakfast based on their characteristics and the need to take medication.

The Lis Pavilion will be home to the researchers, who will have the materials and space needed to carry out the assessments in an organized and comfortable way for the participants. In addition to the above, the Lis Pavilion also has a room where the QoL and well-being assessment scales will be applied individually and without distracting stimuli that could compromise the participant's performance.

Information regarding the procedures and objectives will be provided by the research team, who will also be available to clarify any doubts that may arise. Only the principal investigator will be aware of the allocation of subjects to groups, so the research team carrying out the assessments will be unaware of this information and will remain impartial.

2.7. Instruments

2.7.1. Anthropometry and Body Composition

To measure the participant's height, a stadiometer will be used. The participants will stand barefoot on the platform, leaning against the platform post, looking forward, with their upper limbs alongside their body.

Body composition will be calculated using bioimpedance equipment (Tanita BC-50, Arlington Heights, IL, USA) in which the participant must be barefoot, with their feet in contact with the electrodes. The following data will be collected from each participant: weight, BMI, muscle mass (kg), and fat mass (kg).

2.7.2. Handgrip

To measure upper limb strength, a handgrip test will be carried out using a hand dynamometer. Its reliability and validity have been confirmed by Cabeza-Ruiz et al. [14] and Oppewal and Hilgenkamp [33] and the procedures recommended by the Brockport Fitness Test Manual [34] will be used.

To perform the test correctly, the participant must place their upper limbs alongside their body and perform the hand grip.

2.7.3. Functional Capacity

The Fullerton functional test battery [35] will be used to assess the participants' physical fitness. Thus, to assess the strength and endurance of the lower limbs, the 'sit to stand' test will be carried out, which is feasible and reliable for people with IDD [36,37]. To perform the test, the participant must be seated in the center of the chair, with their back straight, feet shoulder-width apart and fully supported on the floor. When the coach gives the 'start' signal, the participant must stand up, perform the maximum extension (vertical position), and then return to the starting position. The number of repetitions performed in 30 s will be counted and the participant is encouraged to complete as many repetitions as possible.

To assess aerobic endurance, the '6-min walk test' will be used, which is valid and reliable for the study population [38]. For the test to be carried out correctly, the participant must cover the maximum distance in 6 min without running, so at the 'start' signal, the participant is instructed to walk as quickly as possible around the distance marked with cones. If necessary, participants can stop and rest, then sit down and resume the route.

To assess physical mobility, namely speed, agility, and dynamic balance, the test evaluated by Cabeza-Ruiz et al. [14] will be used. The participant will start the test sitting on a chair, with their hands on their thighs and their feet fully flat on the floor. At the 'start' signal, they should get up from the chair and walk as quickly as possible (without running) around the cone that is 2.44 m away, return to the chair, and sit down. The participant should be informed that the test is assessed by calculating the time taken from getting up from the chair to sitting down again.

2.8. Quality of Life

QoL will be assessed using the Portuguese version of the Personal Outcomes Scale [15]. This scale consists of two versions: self-report, answered by the participants, and report by third parties, professionals, or family members who have known the individual for at least 3 months in different contexts. The Personal Outcomes Scale covers eight domains, with five questions each, totaling forty questions. Each question has three Likert response options, such as often, sometimes, or never. This scale makes it possible, among other things, to assess the impact of interventions, providing crucial information for improving their quality, as well as promoting credible and sustainable practices [15].

2.9. Well-Being

Two self-report scales will be used to assess well-being: the Satisfaction with Life Scale, Portuguese version [39], and the Positive and Negative Affect Schedule, Portuguese version [40].

The Satisfaction with Life consists of five questions, each with seven possible answers ranging from 'totally disagree' to 'totally agree'.

The Positive and Negative Affect Scale consists of ten questions, with five answer options ranging from 'not at all or very slightly' to 'extremely'.

2.10. Procedures

As a first step, the principal investigator will explain the procedures and objectives of the study, as well as the potential benefits, risks, and time needed to carry out the project to each of the potential participants, their families/guardians, and the management of the institutions. Subsequently, participants who meet the study's inclusion criteria and wish to take part in the study, as well as their family members/guardians and the management of the institutions, will sign an informed consent form.

Once the informed consent forms have been obtained, an initial assessment of the participants will be carried out and they will be allocated (based on their interests and availability to be involved with PE programs) to the following groups: (i) the experimental group and (ii) the WCG. After the baseline assessment, the 36-week intervention program will begin. After this period, the final evaluation of the groups will be carried out by

an evaluator who is not part of the group, and the same will happen for the follow-up evaluation, 3 months after the end of the program.

Participants must attend at least 75% of the sessions; otherwise, they will continue to benefit from the intervention plan but will not be considered for the study.

2.11. Statistical Analysis

Descriptive statistics will be used, and normality and homogeneity will be checked using the Shapiro–Wilk test and the Levene test, respectively. A mixed 2 × 3 analysis of variance (ANOVA) was conducted with the delivery method as the between groups (WCG and EG) factor and moments (baseline assessment, final assessment, follow-up assessment) as the within factor. Effect sizes were evaluated as trivial (0–0.19), small (0.20–0.49), medium (0.50–0.79), and large (0.80 and greater), as suggested by Cohen [41]. A p-value of <0.05 will be assumed. The data will be processed using the IBM SPSS Statistics v28 program.

3. Adverse Events

Considering that people with IDD tend to have a more sedentary lifestyle, which can contribute to early signs of fatigue or discomfort, a medical team from the institution will be available before, during, and after the intervention program to monitor participants' general health. If any signs of fatigue, injury, discomfort, or muscle pain happen during the intervention program or evaluation tests, the medical team will be ready to address these concerns and evaluate the participants' well-being.

The principal investigator, as well as any of the technicians accompanying the participants during the intervention program sessions, will be available to answer any questions, help, and advise the participants.

In the event of any adverse outcome, this will be recorded, described, and presented in future publications.

4. Participation Attendance/Adherence

Participants must attend and take part in at least 75% of the sessions to be considered for the data processing phase. The participation of everyone in the sessions will be recorded in green if the participant attends and participates in the session and in red if they do not attend or participate in the session.

5. Discussion

This study will allow us to verify the possible benefits of implementing a 36-week intervention program based on sports on the physical fitness, QoL, and well-being of people with IDD. It will also be an important tool for understanding the impact that detraining can have on physical fitness, QoL, and well-being.

Despite the lack of studies exploring the effect of practicing sports in this population, it is expected that the intervention will provide positive changes in the variables under study, considering other studies, with different populations, where it is possible to verify the positive impact of practicing sports in terms of physical fitness, QoL and well-being [42–44]. As verified in the pilot study carried out by Tomé et al. [45], the authors analyzed the effects of a PE program, which included components related to sports on the levels of autonomy, functionality in activities of daily living, and physical fitness of people with IDD. After the end of the intervention program, significant improvements were observed in functionality (self-report and proxy) and body composition variables, but not in physical fitness variables [45]. This lack of improvement may be attributed to the weekly frequency and short duration of the pilot project. However, the intervention program seems to have contributed positively to improving the perception of autonomy in activities of daily living and body composition [45], serving as a good indicator for future research. In this context, the intervention program in this study will consist of a greater number of sessions and will take place over 36 weeks, will be exclusively based on sports, and will consider the participants' opinions throughout the sessions. This way, we intend to make the sessions as

attractive as possible for participants, thus reducing the possibility of dropouts throughout the program.

As far as the WCG is concerned, no changes are expected in the variables analyzed, since the participants will maintain their usual activities. It should be noted that if the intervention program is shown to be beneficial for the experimental group, the WCG will have the opportunity to benefit from the same intervention program after the end of the study. Participants in this study are not randomized to group, nor will we control for any baseline differences between groups. We acknowledge that this selection bias is a limitation that may result in differences being observed that are not real, either with an overestimation or underestimation of the benefit or harm.

The study we are about to initiate is crucial for the development of knowledge in this area and could be a starting point for further research in this area and an effective tool for reducing some of the barriers that hinder/make it impossible to practice PA (e.g., short duration of intervention programmers, lack of motivation) [13,29]. We intend to contribute with implications for practice, providing new interventions and strategies that could be effective and contribute to a paradigm change associated with the high levels of sedentary behavior in the population under study. With the realization of this project, we hope to create useful and effective guidelines for physical education teachers and exercise technicians to help them promote the practice of sports as a way of developing physical fitness, reducing sedentary lifestyles, and, essentially, the QoL and well-being of this population.

6. Ethics and Dissemination

Any changes to the protocol will be agreed upon by the research team and formally communicated to the Ethics Committee of the University of Beira-Interior prior to their implementation (Ethics Committee Code No. CE-UBI-Pj-2023-061).

The sample will be made up of individuals aged between 18 and 65 with IDD who, due to the cognitive limitations associated with the diagnosis, may have difficulties understanding the informed consent form. Therefore, it will be written in simple, accessible language and given not only to the individuals eligible for this study but also to their carers/guardians. As such, it is necessary to guarantee that there will be no secondary gain on the part of the carer and that the opinion of the subject involved in this study will be taken into consideration.

Informed consent will include all clarifications about the study, its objectives, development phases, possible risks and benefits of participation, informing them that they can withdraw at any time without repercussions and that participation will not compromise their physical or psychological integrity, ensuring the confidentiality and anonymity of the data collected. In addition to informed consent, in this case, it is also necessary to obtain informed assent from the participants. This is an agreement to take part in scientific research, considering the existence of a lesser understanding of what is expected.

Each participant will be given a unique coded identification number to maintain their confidentiality, and all experimental data will be recorded using these codes.

The evaluated data will be collected and stored on a computer to which only the principal investigator will have access, and the data will be used exclusively for research purposes. The data will be kept for a period of 5 years after the end of the research and will then be permanently deleted.

After the end of this study, the control group will have the opportunity to take part in a program like the one administered to the experimental group.

The results obtained in this study will be published and communicated, regardless of the magnitude or direction of the effect. Communication with the scientific community will be carried out through participation in conferences and/or congresses.

Author Contributions: Conceptualization, S.D., A.M.C. and R.A.; methodology, S.D., A.M.C. and R.A.; software, S.D., A.M.C. and R.A.; validation, M.J., D.M. and R.M.; formal analysis, A.M.C., M.J., D.M., R.M. and R.A.; investigation, S.D., A.M.C. and R.A.; resources, S.D., A.M.C. and R.A.; data curation, S.D., A.M.C. and R.A.; writing—original draft preparation, S.D., A.M.C. and R.A.; writing—review and editing, S.D., A.M.C. and R.A.; visualization, A.M.C., M.J., D.M., N.A., F.R., R.M. and R.A.; supervision, A.M.C. and R.A.; project administration, A.M.C. and R.A.; funding acquisition, S.D., A.M.C., M.J., D.M., R.M. and R.A. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: This study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of the University of Beira-Interior (protocol code No. CE-UBI-Pj-2023-061, 14 January 2024) for studies involving humans.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the patient(s) to publish this paper.

Data Availability Statement: All data supporting were included in this paper.

Conflicts of Interest: The authors declare no conflicts of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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